



Food and Drug Administration Rockville MD 20857

NDA 50-567/S-016

Allergan, Inc. Attention: Elizabeth Bancroft Senior Director, Regulatory Affairs 2525 Dupont Drive P.O. Box 19534 Irvine, California 92623-9534

Dear Ms. Bancroft:

Please refer to your supplemental new drug application dated October 27, 2000, received October 30, 2000, submitted under the Federal Food, Drug, and Cosmetic Act for Polytrim (trimethoprim sulfate and polymyxin B sulfate ophthalmic solution).

We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This supplemental new drug application provides for revised draft labeling of the package insert to add a Geriatric Use subsection to the Precautions section. The additional text is as follows:

Geriatric Use: No overall differences in safety or effectiveness have been observed between elderly and other adult patients.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling of the package insert submitted October 27, 2000.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-567/S-016." Approval of this submission by FDA is not required before the labeling is used.

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If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2 FDA 5600 Fishers Lane Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Lori M. Gorski, Project Manager, at (301) 827-2090.

Sincerely,

Wiley A. Chambers, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic
Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research